

REMARKS

Status of the Claims

No amendments are currently presented.

Claims 1-3 and 5-7 are currently pending and under consideration.

Double Patenting

The Examiner has provisionally rejected claim 1 on the grounds of nonstatutory obviousness-type double patenting over claim 1 of copending Application No. 10/532,319.

Application No. 10/532,319 has been allowed and the issue fee was paid on March 11, 2010, but as of the filing of this response the patent has not yet issued. Accordingly, Applicants submit if these provisional rejections are the only outstanding rejections, the present claims should be allowed.

Applicants will consider filing a Terminal Disclaimer when the present claims are indicated as otherwise allowable and the '319 Application issues as a patent.

Claim Rejections – 35 USC §103

The Examiner has rejected claims 1-3 and 7 under 35 USC 103(a) as being unpatentable over Edwards et al in view of Forsman, Bergeron, Bergeron '564, Kunsch '98, Kunsch '97, Naimi, Lowe and Buck. (Final Action page 6). The Examiner asserts, in part, that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have adjusted the teaching of Edwards in light of the other cited prior art to arrive at the claimed invention with a reasonable expectation for success. (Final Action pages 6-17)

Applicants respectfully traverse the rejections.

The Examiner cites Edwards Figure 1 as teaching claim 1 step bca). (Final Action page 7)

Applicants assert that Figure 1 does not teach monitoring hybridization of each of said hybridization reagents at a pre-selected temperature, said hybridization being indicative of at least the genus of said pathogenic organism present in the sample as required by claim 1 step bca) of the instant invention. Step bca) requires monitoring of hybridization at a single pre-selected temperature; the determination of hybridization is made by measuring the cycle number at which a positive amplification signal could be detected. The detection of amplification signal determines at least the genus of the pathogenic organism. Support for step bca) is found throughout the specification as filed, including the Examples, and for example in the following:

“The term ‘indicative for at least the genus’ shall mean that if a hybridization signal is occurring in step bba), then it can be concluded for step c) that a pathogenic organism of a certain genus, respectively, may be present in the sample collected from the patient.”

(specification as filed page 18 lines 6-9. *Note: presently claimed step bca) was previously termed “bba”*).

Further discrimination to the species level of the pathogenic organism is then performed by a melting temperature analysis according to step bcb) which provides monitoring temperature dependence of hybridization, said temperature dependence being indicative of at least the species of said pathogenic organism.

“The monitoring step bbb) preferably is performed once a sufficient number of cycles Cp were performed to amplify any target sequence present up to a level to be detectable via temperature dependence. That is usually coinciding with the amount of nucleic acid detectable through probe hybridization, i.e. as soon as there is a clearly positive signal in step bba) measured, step bbb) can be performed. Cp is preferably between 20 and 50.”

(specification as filed page 22 lines 3-8. *Note: presently claimed step bca) was previously termed “bba”, and presently claimed step bcb) was previously termed “bbb”*)

Both monitoring of hybridization AND monitoring of temperature dependence are required to achieve the methods of instant claim 1.

In contrast, Edwards Figure 1 provides only a melting temperature profile and does not provide the required step of monitoring hybridization of each of said hybridization reagents at a single pre-selected temperature. The Examiner is in error in citing Edwards Figure 1 as teaching claim 1 step bca). The data of Figure 1 is generated from a temperature range from 40°C to 95°C; no data is provided in Figure 1 of the detection of hybridization at a single temperature (Edwards Materials and Methods p 3048 column 1 and Figure 1). Further, Edwards provides no teachings relating to step bca) outside of Figure 1, and Edwards does not teach or suggest the method as provided by instant claim 1 that requires both steps bca) and bcb) providing both genus and species information in a single reaction vessel.

Edwards does not teach or suggest a method comprising both a genus and a species determination as provided in the instant invention. Edwards provides a direct species-only determination by melting curve analysis without any proceeding genus determination; in fact, Edwards only provides teachings on one genus – *Staphylococcus*. When samples comprising multiple genera are tested in the methods provided by Edwards without a genus determination, it is

possible that the different genera could result in similar melting temperature profiles. For example, in the methods of Edwards, testing of a sample comprising both *E. coli* and *S. aureus* together in one reaction vessel may give a single peak at one melting temperature, leading to ambiguous results. Edwards does not provide for testing of such a sample with multiple genera. The methods of the instant invention do provide for the determination of multiple genera and species. This separate genus and species identification enables one of skill in the art to determine in a single reaction vessel precisely the genus and species (or, multiple genera and species) that may be present in a clinical sample. The methods provided in instant claim 1 allow for simultaneously detecting and identifying a broad range of pathogenic organisms of interest.

Edwards does not teach all of the required claim elements of claim 1 or its dependents. None of the other art cited by the Examiner in combination with Edwards teaches or suggests the method of claim 1 or its dependents. Applicants respectfully submit that the Examiner has not provided a *prima facie* case of obviousness because the combination of Edwards, Forsman, Bergeron, Bergeron '564, Kunsch '98, Kunsch '97, Naimi, Lowe and Buck does not anticipate each every limitation set forth in the claims.

The Examiner has rejected claim 5 under 35 USC 103(a) as being unpatentable over Edwards et al in view of Forsman, Bergeron, Bergeron '564, Kunsch '98, Kunsch '97, Naimi, Lowe and Buck as applied to claims 1-3 and 7, and further in view of Jannes. (Final Action page 17). Further, the Examiner has rejected claim 6 under 35 USC 103(a) as being unpatentable over Edwards et al in view of Forsman, Bergeron, Bergeron '564, Kunsch '98, Kunsch '97, Naimi, Lowe and Buck as applied to claims 1-3 and 7, and further in view of Loeffler. (Final Action page 18).

Applicants assert that neither Jannes nor Loeffler teach or suggest the claim elements missing from Edwards as detailed above, requiring both steps bca) and bcb) providing both genus and species information in a single reaction vessel. Therefore the combination of the cited art does not anticipate each and every limitation set forth in the claims. Thus, the Examiner has not established a *prima facie* case of obviousness.

For the reasons provided above Applicants respectfully request reconsideration and withdrawal of all of the §103 rejections of independent claim 1 and all other claims depending from claim 1.

CONCLUSION

Applicants respectfully request entry of the present RCE. In view of the above, Applicants believe all claims now pending in this Application are in condition for allowance. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-730-8566.

The commissioner is hereby authorized to charge the amount of \$810, the fee pursuant to 37 CFR §1.114, to Deposit Account No. 50-0812. Please grant any additional extensions of time that may be required to enter this RCE and charge any additional fees or credit any overpayments to Deposit Account No. 50-0812.

Please direct all future correspondences to: Customer No. 22829.

Respectfully submitted,

Date: April 20, 2010

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